13. VACCINE STORAGE UNITS

The following information outlines the storage unit requirements of the Montana VFC Program.

General Requirements

Refrigerators and freezers used for storing VFC vaccine must (*VFC Operations Guide*, M-6, page 8):

- Maintain required vaccine storage temperatures year-round:
  - Refrigerator: 35° to 46°F (2° to 8°C)
  - Freezer: 5°F or colder (-15°C or colder)
- Hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- Have a working National Institute for Standards and Testing (NIST)- or American Society for Testing and Materials (ASTM)-calibrated thermometer inside each storage compartment (See Section 14)
- Be dedicated to vaccine storage (Food and beverages are not allowed in vaccine storage units.)

Combined Versus Stand-Alone Units

Two types of storage units are acceptable:

- Combined refrigerator/freezer units that have separate external doors for each compartment
- Stand-alone refrigerators and freezers

Combined units are those that have a refrigerator and freezer compartment in one appliance. Stand-alone units have just one compartment that is either a refrigerator or freezer. In general, stand-alone units are a better choice for vaccine storage because they are better able to maintain proper vaccine storage temperatures

Dormitory-Style Storage Units

Dormitory-style (also called "bar-style") refrigerator/freezer units are those where the freezer is contained within the refrigerator, and both are accessed by one external door. Please note that the term "dormitory-style" does not refer to the size of the unit. It refers to the location of the freezer within the refrigerator compartment. These units cannot reliably maintain vaccine storage temperatures. The CDC prohibits the use of dormitory-style storage units for the *permanent* storage of VFC vaccine.

Figure 1 Dormitory-Style Refrigerator/Freezer

Policy on Dormitory-Style Storage Units:

- Beginning with the 2011 re-enrollment, VFC providers are prohibited from using dormitory-style storage units for permanent storage of VFC vaccine.
- Permanent storage is defined as that involving more than one day's supply of vaccine for longer than one daily work shift (12 hours).
- The practice of using dormitory-style units for *temporary* storage of VFC vaccine is allowed for those providers already using the units in this capacity (as of February 1, 2011) and as long as certain conditions are met.
- Temporary storage is defined as that where only one day's supply of vaccine is stored for one workday (no more than 12 hours). Vaccine is returned to permanent storage at the end of the day.
- Providers wishing to continue to use dormitory-style units for temporary storage of VFC vaccine must agree to certain conditions and obtain written approval from the Montana Immunization Program. Please contact the Immunization Program for more information.
- VFC vaccine storage units acquired for VFC vaccine after February 1, 2011 must not be dormitory-style units regardless of whether they are used for temporary or permanent storage.

Domestic Grade

Domestic (or "household") quality storage units are those typically found in homes and sold at retail appliance stores. Domestic grade appliances can be used to store VFC vaccine as long as combined refrigerator/freezer units have a separate external door for the refrigerator and freezer compartments and are not dormitory-style units (See *Dormitory-Style Units* above).

Other desirable features include:

- Separate temperature controls for refrigerator and freezer
- Automatic defrost cycling (i.e., "frost-free")
- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Undesirable features include:

- Manual defrosts—These units accumulate frost and ice on the walls of the freezer and cooling coils, and require periodic "defrosting." If you have a manual defrost unit you must arrange alternate vaccine storage and temperature tracking while you defrost your appliance.
- Single-thermostat units—These are combined units with a single thermostat dial that controls both the refrigerator and the freezer. This configuration makes it difficult to maintain appropriate temperatures in both compartments and increases the likelihood of freezing vaccine in the refrigerator. **Please note** that The Montana Immunization Program does not prohibit the use of single-thermostat units. However, such units should be monitored carefully. If temperature excursions and vaccine waste occur, you will be required to upgrade to a dual temperature control model.

Laboratory/Pharmacy-Grade

Laboratory- or pharmacy-grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmaceutical setting. These are the highest quality option for storing VFC vaccine. Laboratory-grade appliances come with safety, temperature control, and security options typically not found on domestic units. Although usually more expensive, they come in a wide variety of sizes, configurations, and prices, including moderately priced under-counter models ideally suited for small clinics.

Size Determination

Your VFC vaccine storage unit must be able to store the year's largest supply of vaccine including ice packs and water bottles used to stabilize temperatures. It also must be large enough to allow spacing between vaccine packages for proper air circulation (See Vaccine Placement, page 51).

To determine the size storage unit you need, calculate the largest number of doses you will have on hand during the year for both your refrigerator and freezer. Be sure to include seasonal influenza and private stock if it will all be stored in the same unit. Multiply the maximum doses by 1.25 to account for package spacing. Use this number (maximum doses) and the chart below to determine the minimum cubic feet of storage space you will need.

Table 1 Minimum Cubic Feet of Storage Space Based on Maximum Doses

Refrigerator		Freezer	
Maximum Doses	**Minimum Cubic Feet Required**	**Maximum Doses**	**Minimum Cubic Feet Required**
1001–2000	40	501–600	7–14.8
900–1000	36	201–500	5–5.6
801–900	21–23	0–200	3.5–4.9
701–800	17–19.5		
401–700	11–16.7		
100–400	4.9–6.1		

Setting Up your Storage Unit

Follow the procedures below when acquiring a new storage unit, moving an existing unit, or reestablishing a unit after a power outage or repair.

Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- For proper cooling and heat exchange, locate the storage unit in a well-ventilated space away from direct sunlight and with 4 inches between the unit and surrounding walls, cabinets, and appliances.

- Do not block the motor compartment, which is usually located in the back or side of the unit.

Electrical Supply

- Place the storage unit near enough to an outlet so that the cord is not a tripping hazard and an extension cord is not necessary.
- Make sure the outlet is not controlled by a light switch.
- Place a "DO NOT UNPLUG" sign next to the outlet ***and its controlling circuit breaker***. If these are not accessible or visible, place the sign as near as possible so that anyone accessing the outlet or circuit breaker is likely to see it.
- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- If you have a backup power supply for your facility, make sure it is in working order, tested regularly, and that your storage units are connected to the system.
- If you do not have a backup power supply, arrange at least one alternate vaccine storage location that has proper refrigerator and freezer units, temperature monitoring capability, and backup power where your vaccine can be moved in the event of a power outage. Record this information in Section 12 of this document.

Temperature Stabilizing

- Plug the unit into the electrical outlet and set the temperature to fall within the following ranges:
    - Refrigerator: 2° to 8°C (35° to 46°F)
    - Freezer: -15°C or colder (5°F or colder)
- If the unit has a thermostat, set to the following target temperatures:
    - Refrigerator: 4°C or 40°F
    - Freezer: -20°C or -5°F
- If the unit has a controller with numbers or words (e.g., "colder"), set as follows:
    - Refrigerator: Set slightly warmer than mid-range.
    - Freezer: Set to mid-range.

Please note – For most numbered temperature dials, the higher the number the colder the temperature. Check your owner's manual to avoid improper adjustments.

- Place a working NIST- or ASTM-calibrated, continuously monitoring thermometer inside each storage compartment in a central location away from walls, vents, fans, and cooling coils. The Montana Immunization Program supplies thermometers to VFC providers (see Section 14).
- Place several containers of water along the inside walls, in door racks, and vegetable bins ("crispers") of the refrigerator, and several frozen packs along the walls and in the door rack of the freezer. These will help stabilize temperatures when the door is open and in the event of a power outage. Do not impede air flow by over-filling with water bottles and ice packs.
- Make sure doors close tightly and seals are intact.
- Allow the unit to stabilize overnight and check temperatures in the morning.

- Adjust the dial or thermostat until the target temperature is achieved and held for at least 3 days. Log temperatures at least twice a day during the adjustment period.
- Once the temperature is in range and stabilized, your storage unit is ready to receive vaccine.

Vaccine Placement

- Place vaccine in the middle of the compartment away from ceilings, walls, vents, fans, and coils. In the refrigerator compartment of combined units, keep vaccine away from the vent or fan channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins. Consider removing vegetable bins to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine "VFC" and keep it physically separated from private stock.
- Keep vaccine in its original packaging and organize by vaccine type. Consider physically separating vaccines with similar names, packaging, or antigens to avoid administration errors.
- Organize packages so that short-dated vaccine is used first.
- If containers are used to organize vaccine, use only open (no lid) containers that allow air to circulate, such as wire baskets or cardboard boxes.
- Never store food or beverages in vaccine storage units. Other biologicals can be stored in vaccine storage units as long as they are physically separated from vaccine to prevent contamination and administration errors.
- Diluent packaged with the vaccine should be stored at the same temperature as the vaccine. Diluent packaged separately from the vaccine can be stored refrigerated or at room temperatures.

Temperature Monitoring

- Monitor and record temperatures twice a day for all VFC vaccine storage units. This is required even when your unit has a continuous monitoring chart or data logger, or a temperature alarm (see Section 14 for thermometer requirements).
- Record the twice-daily temperature readings either on a paper temperature log (provided on our website at www.immunization.mt.gov) or through the imMTrax cold chain management module (See Section 15, page 56 for details). Temperatures logged in imMTrax exclusively (not kept on paper) *must be entered twice daily*. Temperatures logged in imMTrax are automatically archived for at least three years and can be reviewed by providers and the State. Paper temperature logs must be kept for 3 years.
- Do not make temperature adjustments without informing your vaccine manager or alternate vaccine manager. Consider posting a sign discouraging temperature adjustments by unauthorized personnel.
- DO NOT adjust temperatures in the evening or before a weekend when temperatures cannot be monitored.
- When adjusting temperatures, make slight changes to the thermostat or temperature dial and allow the unit to stabilize for 30 minutes. (Check your owner's manual to make sure controller adjustments are in the proper direction.) Check and record the temperature.
- Repeat, until the temperature is comfortably within range and stable.
- Record all temperature adjustments and issues with your storage unit on a Vaccine Storage Trouble-Shooting Log (page 3 of the State-supplied temperature logs). Logging these events will communicate

vaccine storage issues to all staff, and document recurring problems and trends with your unit. This will help catch minor problems early before they lead to major incidents that waste vaccine.

- Be proactive in addressing storage unit issues before they result in vaccine wastage or patient recall situations.

Out-of-Range Temperatures

- If vaccine is exposed to out-of-range storage temperatures that threaten your vaccine, immediately obtain a Vaccine Incident Report from www.immunization.mt.gov and follow steps 1–6 on the report. Call or email the Immunization Program immediately 444-5580 or hhsiz@mt.gov.